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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/980,824      | 03/14/2002  | Gerd Geisslinger     | 016915-0252         | 3370             |

22428 7590 02/12/2004

FOLEY AND LARDNER  
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WASHINGTON, DC 20007

EXAMINER

KWON, BRIAN YONG S

ART UNIT PAPER NUMBER

1614

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/980,824

Applicant(s)

GEISSLINGER ET AL.

Examiner

Brian S Kwon

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Amendments filed 9/12/03 and 10/30/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10, 12-19 is/are pending in the application.
- 4a) Of the above claim(s)    is/are withdrawn from consideration.
- 5) ☐ Claim(s)        is/are allowed.
- 6) ☐ Claim(s)        is/are rejected.
- 7) ☐ Claim(s)        is/are objected to.
- 8) ☒ Claim(s) 10, 12-19 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No.       .
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>      </u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>      </u> | 6) <input type="checkbox"/> Other: <u>      </u>  |

## **DETAILED ACTION**

### ***Status Application***

1. In response to the Office Action mailed June 12, 2003, applicants filed an amendment on September 12, 2003. By the amendment, claims 1-9 were cancelled and claims 10-20 were added. In addition, applicants filed a supplemental amendment on October 30, 2003. By the supplemental amendment, claims 11 and 20 were cancelled and claims 10, 15 and 19 were amended.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 10, 12-16 and 19, drawn to a method of treating a subject suffering from a condition characterized by high human tissue glucuronidase activity or inhibiting human tissue glucuronidase, comprising administering a glucuronidase inhibitor such as verapamil and verapamil derivatives and a suitable pharmacologically compatible adjuvant.
- II. Claims 17-18, a method of selectively activating a glucuronide prodrug in a target tissue, comprising administering to a subject a glucuronidase inhibitor,

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glucuronide prodrug, and glucuronidase bound to a target tissue specific substance.

The inventions listed as Groups I and II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature presented in Group I (ability of verapamil or verapamil derivatives in inhibiting human tissue glucuronidase) appears to be unrelated to the technical feature presented in Group II (ability of a glucoronidase inhibitor in selectively activating a glucuronide prodrug). Therefore, the technical feature linking the inventions of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2. Accordingly, Groups I and II are not linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

**Brian Kwon**  
Patent Examiner  
AU 1614

A handwritten signature in black ink, appearing to read 'Brian Kwon', with a long horizontal line extending to the right.